

### **REMARKS**

Entry of the foregoing, reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 111, are respectfully requested in light of the remarks which follow.

#### **I. Amendments to the Claims**

By the foregoing claim amendments, claims 1, 3, 13, 17, 26, and 29 have been amended as discussed below, and claims 4 and 16 have been canceled.

The amendments to the claims, including cancelation of claims, have been made without prejudice or disclaimer to any subject matter recited or canceled herein. Applicants reserve the right to file one or more continuation and/or divisional applications directed to any canceled subject matter. No new matter has been added, and entry of the foregoing amendments to the above-identified application are respectfully requested.

#### **II. Response to Objections**

**A.** The drawings have been objected to for a number of reasons.

In particular, the Examiner has stated that the drawings have been objected to because elements 11-14, and 20-24 in Figure 4 are not labeled with indicia indicative of their function.

In addition, the Examiner has also stated that the drawings have been objected to under 37 C.F.R. § 1.83(a) for not showing every feature of the invention specified in the claims. In particular, the Examiner has stated that the "input means for being input a preserved distance" and the "controlling not to activate the photosensitive substance in the superficial part of the body located close to the light irradiation means then the lesioned part" must be shown or the feature(s) canceled from the claim(s).

In response, Applicants submit that Figure 4 is described at page 22, line 21 to page 23, line 24 of the specification. The description includes a description of elements 11-14 and 20-24. Further, the "input means" is a component inputting the preservation distance. According to page 28, lines 2 to 8, of the specification, "[t]he preserved distance in the superficial part 41 is determined by the operator based on the information such as the depth and size of the lesion 41 obtained by previously performed ultrasound imaging, CT scan,

plain roentgenography, MRI, etc., and the data is input to the control element 22 (Step S2) . In this case, the shallower area than the depth of the lesion 41 is determined as the preservation distance." Thus, it would have been obvious to a person of ordinary skill in the art that the input means is achieved as one of functions of control element 22. Finally, in order to clarify this point, the claims have been amended by deleting "input means" to make clear that the control means is used to input the preservation distance.

**B.** The amendment filed February 17, 2009 has been objected to under 35 U.S.C. § 132(a) because it allegedly introduces new matter into the disclosure.

Specifically, the Examiner has stated that the phrase "input means for being input a preserved distance" (see claim 1) is new matter.

To expedite prosecution in the present application, and not to acquiesce to the Examiner's rejection, the term "input means" has been deleted from the claims.

**C.** The specification has been objected to as failing to be written "in full, clear, concise, and exact terms."

In particular, the Examiner has stated that a number of terms and phrases remain unclear in the revised specification. The Examiner has provided a number of examples, including "low peak intensity," "high peak intensity."

Applicants traverse this rejection, and respectfully submit that the specification clearly describes the claimed invention.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the objections.

### **III. Response to Claim Rejections Under 35 U.S.C. § 101 - Non-Statutory Subject Matter**

At page 7 of the Office Action, claims 26-28 have been rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter.

In particular, the Examiner has stated that claim 26 positively recites the tissue.

In response, claim 26 has been amended to read: "The photodynamic therapy equipment according to claim 17, further comprising a catheter."

**IV. Response to Claim Rejections Under 35 U.S.C. § 112**

**A.** Claims 1-30 have been rejected under 35 U.S.C. § 112, first paragraph, as purportedly failing to comply with the enablement requirement.

In particular, the Examiner has acknowledged that the control means is enabled to control the operational parameters of the light. However, the Examiner has further stated that the control means is not enable to process the additional variables recited in the claims, and that the "input means . . ." is not sufficiently described nor enabled.

**B.** Claim 13 has been rejected under 35 U.S.C. § 112, first paragraph, as purportedly failing to comply with the enablement requirement.

In particular, the Examiner has stated that the means for "controlling not to activate the photosensitive substance . . ." is not enablingly disclosed.

**C.** Claim 17 has been rejected under 35 U.S.C. § 112, first paragraph, as purportedly failing to comply with the enablement requirement.

In particular, the Examiner has stated that the "means for measuring the cell death rate and providing same . . ." is not disclosed.

**D.** Claim 1 has been rejected under 35 U.S.C. § 112, first paragraph, as purportedly failing to comply with the written description requirement.

In particular, the Examiner has stated that the "input means for being input a preserved distance" is new matter.

**E.** Claim 17 has been rejected under 35 U.S.C. § 112, first paragraph, as purportedly failing to comply with the written description requirement.

In particular, the Examiner has stated that the control means calculating an irradiation condition based on measurement of result rate of cell death is new matter.

**F.** Claims 1-30 have been rejected under 35 U.S.C. § 112, second paragraph, as purportedly being indefinite for a number of reasons.

These rejections are respectfully traversed, as follows

Concerning "high peak intensity" and "low peak intensity"

The examiner mentioned that the terms "high peak intensity" and "low peak intensity" are ambiguous.

To expedite prosecution in the present application, and not to acquiesce to the Examiner's rejection, the claims have been amended by replacing the terms "high peak

intensity" and "low peak intensity" with the terms "high intensity" and "low intensity", respectively, in claims 1, 13, 16 and 29.

Applicants further note that light intensity does not mean optical power. To make it clear, Applicants have added a phrase, "the light irradiating intensity, with or without changing an optical power", in the independent claims. The difference between light intensity and optical power would have been recognized by a person of ordinary skill in the art (see, e.g., [http://www.rp\\_Lphotonics.com/optical intensity.html](http://www.rp_Lphotonics.com/optical%20intensity.html)).

Concerning "cell fatality rate" and "cell death rate"

The examiner cited Webster's dictionary and mentioned that the terms "cell fatality rate" and "cell death rate" are ambiguous. However, Applicants have defined these terms in the specification. Page 19, lines 26 to 31, for example, indicates that "[t]he rate of cell death means the rate of cells damaged by an action of activation of the photosensitive substance. Further, the cell fatality rate means a criterion for the rate of cell death, in which function of the organ becomes unrecoverable by an action of the photosensitive substance." This description clearly defines the meanings of "cell fatality rate" and "cell death rate".

Concerning the enablement rejection (see page 5, line 14 of the Office Action)

The examiner indicates that light cannot be controlled since depth or size of lesioned part is unknown. However, page 28, lines 2 to 7 of the specification indicates that "[t]he preserved distance in the superficial part 41 is determined by the operator based on the information such as the depth and size of the lesion 41 obtained by previously performed ultrasound imaging, CT scan, plain roentgenography, MRI, etc., and the data is input to the control element 22 (Step S2)." Thus, the depth and size of lesioned part is given by preliminary diagnosis and so on.

In addition, with regard to claim 17, the examiner also mentioned that irradiation conditions cannot be calculated even if certain parameters are determined. Applicants assume that the examiner does not like term "calculate" in claim 17. Thus, claim 17 has been amended to recite the word "control" instead of "calculate".

**V. Response to Claim Rejections Under 35 U.S.C. §§ 102 and 103**

A. Claims 1, 2, 4-6, 10-12, 17, and 22-25 have been rejected under 35 U.S.C. § 102(b) as purportedly being anticipated by Parker et al. (U.S. Patent No. 4,592,361).

**B.** Claim 3 has been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over Parker et al. (U.S. Patent No. 4,592,361), in view of Prasad et al. (U.S. Patent Publication No. 2003/0022105).

**C.** Claims 7-9 and 26-28 have been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over Parker et al. (U.S. Patent No. 4,592,361), in view of Selman (U.S. Patent No. 5,514,669).

**D.** Claims 13-16 and 29-30 have been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over Parker et al. (U.S. Patent No. 4,592,361), in view of Dumoulin-White et al. (U.S. Patent No. 6,413,267) and Dougherty (U.S. Patent No. 5,145,863).

These rejections are respectfully traversed.

To expedite prosecution in the present application, and not to acquiesce to the Examiner's rejection, claims 4 and 16 have been deleted and the independent claims have been amended to recite that a superficial part, which is shallower than the lesioned part, is a healthy part.

The present invention can treat (damage) only the deep-lying lesioned part while preserving the normal healthy superficial region. For making it possible, the control means is preliminary input the depth information of the lesioned part. Based on the depth information, the control means can set the light irradiating peak intensity strong enough in the light of attenuation of light intensity in the normal healthy superficial region so that the light is allowed to pass while maintaining the high peak intensity for not activating the photosensitive substance through the healthy superficial part. Thus, the light can activate the photosensitive substance only at the lesioned part.

The cited documents do not teach or suggest the recited invention. In particular, they do not disclose that the light irradiating peak intensity is set based on the depth information of the lesioned part. The above point is supported by specification at least at page 28, lines 2-8, and 15-22, and page 29, line 19 to page 30, line 2.

Accordingly, Applicants respectfully request reconsideration and withdrawal of these rejections.

**CONCLUSION**

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this Amendment and Reply or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney so that prosecution of this application may be expedited.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: September 22, 2009

By:

A handwritten signature in dark ink, appearing to read "Lisa E. Stahl", is written over a horizontal line.

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